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REMARKS

Upon entry of this amendment, claims 1-7 will be pending in the above-identified application. Claim 14 was cancelled and claims 1-7 have been amended herein.

Reconsideration and allowance of all claims are respectfully requested in view of the following remarks. The amendments relating to claim of priority to U.S. Patent No. 6,403,341, and as to the usage of trademarks DEEP VENT and KLENTAQ1 requested in the Office action have been submitted.

Section 101

Claim 14 was rejected under 35 U.S.C. 101 on the asserted basis that the claimed invention is directed to non-statutory subject matter. Claim 14 has been cancelled. Hence, this rejection is moot.

Section 102 - Mirkin

Claim 1 was rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,709,825 (Mirkin et al.). Applicants respectfully traverse this rejection of claim 1 as amended and urge that it be withdrawn.

Claim 1 of the instant application as amended sets forth a kit which contains *functionally related reagents and instructions* whereby a *precipitate* of magnesium phosphate is provided at temperatures below 34°C. This is clearly the product claimed and is at the heart of the novel improvement - giving the lab technician a more convenient kit to use for amplification.

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The elements of a patent claim must be read as a whole, including both the property of the kit components to form a precipitate, when the instructions are followed, and the inclusion of the kit instructions themselves. These claim elements may not be ignored, and if not found in, nor obvious in view of the prior art, the invention claimed as a whole is therefore patentable. See *In re Gulack*, 703 F.2d 1381 (Fed.Cir. 1983); *In re Ngai*, 91 Fed.Appx. 153 (Fed.Cir. 2004).

Hence, it would be inappropriate for the Patent Office to "read out" the claim elements of 1) "a container comprising a source of phosphate ions and a container comprising a source of magnesium ions, wherein combining the source of magnesium ions and the source of phosphate ions in accordance with instructions supplied in the kit forms a precipitate . . . " and 2) "Instructions for using . . . " Since neither of these claim components of amended claim 1 are found anywhere in Mirkin et al., the rejection under Sec. 102(e) must be withdrawn.

Applicants specifically traverse the statement in the instant Office action that the "wherein combining" element may be ignored. This language clearly informs the reader of the patent claim that the kit contains the necessary ingredients having the characteristics disclosed in the specification needed to form the essential magnesium precipitate at the desired temperature, and is not merely a recitation of a method of combining sources of ions. Moreover, not merely any source of magnesium ions and source of phosphate ions are capable of forming a precipitate at a temperature below 34°C, hence the inherency suggested to be in the prior art (see Office action p.4, para. 7) has not been demonstrated.

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Section 103 - Usuda, Ahren, Yamane, Hyland and Barnes

Each of the rejections under Sec. 103(a) for obviousness similarly fail because there is no suggestion to include either 1) "a container comprising a source of phosphate ions and a container comprising a source of magnesium ions, wherein combining the source of magnesium ions and the source of phosphate ions in accordance with instructions supplied in the kit forms a precipitate . . ." and 2) "instructions for using . . ." as required in each of the rejected claims, as amended. Accordingly, applicants urge that the rejections under Sec. 103(a) be withdrawn.

Claim 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,673,576 (Usuda et al.) in view of Ahren (Biochemical, Reagent Kits Offer Scientists Good Return on Investment, 1995).

Claims 1-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,033,851 (Yamane et al.) in view of Ahern (Biochemical, Reagent Kits Offer Scientists Good Return on Investment, 1995).

Claims 4-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,033,851 (Yamane et al.) in view of Ahern (Biochemical, Reagent Kits Offer Scientists Good Return on Investment, 1995), as applied to claims 1-3, and in further view of U.S. Patent No. 4,972,602 (Hyland et al.).

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,033,851 (Yamane et al.) in view of Ahern (Biochemical, Reagent Kits Offer Scientists Good Return on Investment, 1995), as applied to claims 1-3, and in further view of U.S. Patent No. 5,436,149 (Barnes et al.).

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However, each of these references merely recite disparate instances wherein magnesium and phosphate appear together in a reaction mix, without any teaching of the desirability for, or much less, the likely success of a kit, having the qualities essential for using a magnesium precipitate to conduct an improved "hot start" amplification. Hence, when the claims are *read as a whole*, as required (see above), the invention as claimed is clearly novel and not obvious.

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CONCLUSION

Applicants have included a Credit Card Payment Form in the amount of \$510.00 to cover the three month extension of time fee. The Commissioner is hereby authorized to credit overpayments or to charge any deficiency in connection with this filing to Deposit Account No. 19-3140.

Applicants urge that the application is believed to be in condition for allowance. However, if the Examiner believes that there is any issue remaining which could be resolved by an interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

Dated: May 16, 2005

Respectfully submitted,


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